2. SIDS AND DATA COLLECTION*

2.1 Introduction

This chapter describes the Screening Information Data Set (SIDS), including characterisation and effects data, as well as exposure information, to be collected and collated into a SIDS Dossier by a Sponsor country. It describes the various means which have been developed to assure harmonized presentation of the SIDS for use in OECD Existing Chemicals activities.

For a Sponsor country, collection of SIDS data from industry and other Member countries is a very important procedure for drawing up both a SIDS Dossier and a SIDS Testing Plan for an assigned chemical. Input of the data collected for SIDS (see Section 2.2) can be done using the HEDSET diskette, a hard copy of "Revised OECD HPV Form 1" or a diskette equivalent in Word 6.0, all of which can be obtained through SIDS Contact Points or the OECD Secretariat. Although the choice depends upon the preference of the data submitter, **use of the HEDSET diskette is strongly encouraged.**

The Harmonized Electronic Data SET (HEDSET), which has been developed in co-operation with the European Commission, has become available, together with its manual and an explanatory note, as a device for data collection in the OECD SIDS procedure. By using IUCLID software developed by the European Commission, data in a HEDSET diskette can be transferred to a database easily. In addition, data will be able to be transferred to IRPTC without manual inputting by means of a conversion program. The HEDSET diskette and requirements for its use are described in Section 2.3.

To date, a paper form called "OECD HPV Form 1", which was agreed and distributed in 1990, has been used widely by Member countries. This form was slightly modified in 1993, taking into account the format of HEDSET. The revised form, presented in Section 2.4, can be used instead of HEDSET if necessary. However, it should be noted that it is quite time-consuming to draw up a report from information obtained from various sources using the paper form. Furthermore, inputting the data on the form to computer files will be necessary in the end in order to make the data available to the public through IRPTC. Although it might be slightly easier to edit data by using a PC file of Revised OECD HPV Form 1, it is recommended to collect information using HEDSET if possible.

In Section 2.5, guidance for collection and transmission of exposure information is described.

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* The documents in this chapter were prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to June 1997.

2.2 Content of the Screening Information Data Set (SIDS) [**]

The following lists the content of the Screening Information Data Set (SIDS). In preparing the SIDS, the "Guidance for Meeting the SIDS Requirements" (see Section 3.4) and a Model SIDS Dossier (see Annex 5 to this manual) will help data submitters and SIDS Contact Points understand what kind of data are required and how the data are to be described in HEDSET or the Revised OECD HPV Form 1.

Basic Information

The following data elements on characterisation, exposure and effects are basically required for preparing the SIDS Dossier. The items marked with a dagger (†) are specifically required for inorganic chemicals. Oxidation-reduction potential should also be required for organic chemicals when deemed necessary.

1. General Information
   - Substance Information
   - CAS Number
   - Name (OECD name)
   - CAS Descriptor †
   - Structural Formula
   - Quantity (production ranges expressed as tonnes per year)
   - Use Pattern (categories and types of use, see also next page)
   - Sources of Exposure (exposure information, see also next page)

2. Physical-chemical Data
   - Melting Point
   - Boiling Point
   - Relative Density †
   - Vapour Pressure
   - Partition Co-efficient: n-Octanol/Water
   - Water Solubility
   - Dissociation Constant
   - Oxidation-reduction Potential †

3. Environmental Fate and Pathways
   - Photodegradation (by estimation)
   - Stability in Water (by estimation)
   - Monitoring Data (environmental)
   - Transport and Distribution between Environmental Compartments including Estimated Environmental Concentrations and Distribution Pathways [by estimation, including Henry's Law constant as calculated from data under heading 2, aerosolisation, volatilisation, soil adsorption and desorption calculated using Structure Activity Relationships (SARs)]
   - Aerobic Biodegradability

[**] The content of the SIDS was agreed at the 13th Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals (November 1989). The procedures for collecting and transmitting exposure information were agreed at the Meeting of the Steering Group on Existing Chemicals and confirmed at the 25th Joint Meeting (November 1996).

4. Ecotoxicity
   - Acute Toxicity to Fish
   - Acute Toxicity to Daphnia (If there is concern for possible long-term effects, prolonged/ chronic toxicity testing should be considered in addition to acute tests.)
   - Toxicity to Algae
   - If significant exposure is expected in the terrestrial environmental compartment, efforts should be made to perform appropriate terrestrial toxicity tests. In addition, when aquatic toxicity testing is not possible (e.g. insolubility of the test chemicals), efforts should also be made to perform terrestrial toxicity tests.

5. Toxicological Data
   - Acute Toxicity
   - Repeated Dose Toxicity
   - Genetic Toxicity (two end points, generally point mutation and chromosomal aberrations)
   - Reproduction Toxicity (including fertility and developmental toxicity)
   - Experience with Human Exposure (if available)

It has also been agreed that some data in SIDS are not required for chemicals with limited exposure, such as intermediates (see Section 3.6).

Exposure Information

It was agreed in May 1993 that certain elements of exposure information be part of the SIDS. Such elements included those which were essential to allow effective application of even simple models and methods. However, despite the decision to encourage collection of exposure information, difficulties arose in actual data collection. Therefore, a Task Force under the Steering Group on Existing Chemicals met in June 1995 and made recommendations for effective and efficient procedures for collection and transmission of exposure information, as well as on exposure data elements to be gathered for the SIDS Initial Assessment.

Taking into account the experiences gained in a pilot study based on the recommendations, another approach was proposed and discussed at the 4th SIDS Initial Assessment Meeting held in Tokyo in May 1996. Finally, the Steering Group agreed at its meeting in November 1996 on the following procedures for collecting and transmitting exposure information, which were subsequently confirmed at the 25th Joint Meeting in November 1996:

First Step (Beginning with Phase 5 chemicals)

(a) The Secretariat informs Member countries which chemicals are being sponsored and requests them to collect exposure information on these chemicals, i.e. at the information gathering stage. (Beginning with Phase 6, information giving the rationale for the selection of each chemical is provided for Member countries to easily focus on specific exposure situations.)

(b) Member countries gather easily-available exposure information on the elements in the following list on all the chemicals at this stage and forward it to the relevant Sponsor countries within 6 months.

   - Produced, imported or used?
   - Quantity (production, import and/or export volume)
   - General information on use pattern
   - MAK or equivalent occupational standards
   - Information on classification and labelling
   - National regulatory standards or other measures for management of exposure
   - Other information (e.g. results of workplace monitoring, other information on occupational exposure, information on release to the environment, results of environmental monitoring, information on consumer exposure, safe handling procedures, etc.)

(c) Sponsor countries gather more detailed national exposure information on their own sponsored chemicals.

Second step (Beginning with specific chemicals identified at SIAM4)

- More detailed information will be gathered later by Member countries for specific chemicals, especially those for which a potential hazard has been identified at a SIAM.

Guidance for collection and transmission of exposure information is given in Section 2.5.

2.3 Outline of the Harmonized Electronic Data SET (HEDSET)

HEDSET (Harmonized Electronic Data SET)

HEDSET is a data entry system compiled on diskette with supporting programmes. It has been developed in order to accommodate data on a chemical and allow their transfer to a data export file on diskette, which can then be circulated as necessary. It is written in CLIPPER software and can be run on any type of **IBM compatible PC with a minimum of 640 KB memory and MS-DOS version 3.3 or higher.** It is used after installing on a hard disk (**with minimum of 10 MB free disk space).** Further details are given in a manual. It should be noted that HEDSET does not itself have database or word processor functions. These functions are available through IUCLID software.

The HEDSET comprises the following data items, which were identified and agreed to be necessary for the initial assessment of a chemical:

- general information on a chemical;
- information on producer, importer, etc.;
- physical-chemical properties;
- information on environmental fate and exposure;
- ecotoxicological properties; and
- toxicological properties.

The data elements in HEDSET are essentially the same as those in the Revised OECD HPV Form 1, but with some differences in the numbering system.

For the purpose of promoting user friendliness, HEDSET has many functions for inputting data by means of a glossary, multi-entry facilities, free text data fields, and CAS and EINECS number checking programmes. Although HEDSET will be available in nine EU official languages, only the English version should be used for the OECD work on HPV chemicals.

Print files, made by using the printing function, are ASCII files. They can be printed out directly or can be edited using any word processing software.

Although data inputted on the hard disk of a PC will automatically be converted to CLIPPER format, the data export programme makes ASCII files for transfer to diskette. These export files can be read and incorporated into another PC using the import programme.

Because HEDSET does not have database functions, users cannot electronically compare the data (on two or more chemicals). They may wish to obtain the IUCLID software for this purpose.

It should be noted that, for copyright reasons, modification of the HEDSET diskette is prohibited without the prior permission of the European Commission.

Data Collection Process

It is recommended that the following be used to collect information on HPV chemicals for Phase 4 onwards, in place of the Revised OECD HPV Form 1:

- a PC with HEDSET installed;
- the explanatory note for HEDSET;
- the manual for HEDSET; and
- an export file on diskette for circulation (**only one chemical per diskette**).

The diskette and supporting documents will be distributed to data submitters, (i.e. manufacturers or importers of chemicals) through the National SIDS Contact Points. Data submitters will input the data and send export files on diskettes to the National SIDS Contact Points for onward circulation to Member countries and the OECD Secretariat.

The information in these files will be used nationally for review and/or the initial assessment of the sponsored HPV chemicals, and also at SIDS review procedure and SIDS initial assessment meetings. In addition, the data collected will be made available to IRPTC for wider dissemination. Work is under way on a conversion programme to allow automatic input of HEDSET export file data into the IRPTC database.

IUCLID (International Unified ChemicaL Information Database)

IUCLID is a database software which has been developed by the European Commission in order to deal specifically with data collected using the HEDSET system.

IUCLID is capable to run on different hardware platforms and operating systems. The following operating systems are supported: IBM-AIX (Unix), SCO-UNIX, VMS, DEC-UNIX, SUN SOLARIS and MS-DOS. A corresponding version of the ORACLE database management software is required. To operate ***IUCLID*** on a PC with MS-DOS a disk space of 100 Mbytes and a main memory of 16 Mbytes is required. A PC with a PENTIUM processor is recommended.

IUCLID can import and compile data from export files made under HEDSET. Database functions such as data search, data sorting, etc., as well as printing functions, are included. ASCII files for exporting data can also be prepared, which could be used for circulation instead of HEDSET diskette.

The ***IUCLID*** database software and an explanatory manual is available from the European Commission. Recently, a CD-ROM for Windows which includes non-confidential data concerning HPV chemicals in the EU (i.e. chemicals in Annex I of Regulation (EEC) 793/93) has been made available as a low-cost version of the *IUCLID* database.

2.4 Guidance for the Responder to the OECD Request for Available Data on High Production Volume (HPV) Chemicals: "Revised OECD HPV Form 1"

1. The attached blank form, **Revised OECD HPV Form 1**, is for the provision of available information on HPV chemicals: i.e. a Screening Information Data Set (SIDS) in the form of a "SIDS Dossier". This original HPV Form 1 was agreed and distributed in 1990, then revised in order to achieve full compatibility with HEDSET in 1993. This "Revised OECD HPV Form 1", now fully compatible with HEDSET, is available both in paper form and on a diskette written in Word 6.0 from the National SIDS Contact Points or the OECD Secretariat.

2. Revised OECD HPV Form 1, used for preparing the SIDS Dossier, includes the SIDS Profile and SIDS Summary. These should be filled in after data entry.

3. The information presented should be sufficiently reported and referenced with respect to the substance tested, methods used, endpoints examined and results obtained so as to allow reviewers to make an informed judgement of the quality and suitability of the data.

4. In general, the support data and reports will not be kept confidential. [See also OECD Council Act C(83)98(Final) and its OECD List of Non-Confidential Data on Chemicals.] In exceptional cases, where data are indicated to be confidential, they will be made available for review on a confidential basis by specific experts in each Member country that receives the data. That is, in these cases the OECD Council Act concerning Exchange of Confidential Data on Chemicals [C(83)97(Final)] applies.

5. When a standard test method (e.g. OECD, ISO, DIN, EPA) has been used, it should be identified but it is not necessary to repeat details in the text. When a non-standard method has been used, details of the method, equivalent to those in an OECD Test Guideline, should be provided when possible.

6. When the test method allows the use of alternatives for certain test parameters (e.g. species), the alternatives chosen should be indicated. In the case of aquatic toxicity tests, it is important to indicate whether nominal or measured concentrations were used.

7. If more than one set of data is available for a given item, each set should be submitted. **The preferred results should be identified as "preferred results" and should come first in the set of data of the item** after the data evaluation is over.

8. Under the entry for "Test substance", where possible the purity, percentages of known impurities, and details of any vehicle used should be given.

9. When submitting the test results for any individual data element, the format should, where possible, be based on the corresponding Test Report section described in the relevant OECD Test Guideline.

10. Calculated values must be identified and the calculation method should be cited.

11. Under the section "References", the source of information used to respond to the request should be identified. In general, information should be taken from primary sources and quoting from secondary references such as a book or a review article should be avoided. Indicate the title of the article; journal where study appears; volume; page numbers; and date of report or publication. Where appropriate, indicate "unpublished report", its authors and their affiliation. Lesser details can be cross-referenced within the appropriate individual data element.

12. Where data for the sponsored chemical are not available, the responders are encouraged to submit existing data on related compounds such as:

- isomers which have similar structure activity profiles;
- closely related homologues;
- relevant precursors and breakdown products, along with information on metabolism and degradation.

13. Data elements marked with an asterisk (*****) correspond to those in the Screening Information Data Set (SIDS), and those marked with a dagger (†) are specifically requested for inorganic chemicals.

14. In order to facilitate filling in this form in an appropriate fashion, a Model Dossier has been prepared and is set out in Annex 2 to this Manual. Explanations related to data requested in this form can also be found in the HEDSET Explanatory Note available from the European Commission.

REVISED OECD HPV FORM 1

SIDS DOSSIER
ON THE HPV PHASE . . . . . CHEMICAL

. . . . . .

CAS No. . . . . - . . - .

Sponsor Country : . . . . . .

DATE: . . . . . .

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6. REFERENCES

Note: *; Data elements in the SIDS
†; Data elements specially required for inorganic chemicals

SIDS PROFILE

DATE:

1.01 A.	**CAS No.**	
1.01 C.	**CHEMICAL NAME (OECD Name)**	
1.01 D.	**CAS DESCRIPTOR**	
1.01 G.	**STRUCTURAL FORMULA**	
	OTHER CHEMICAL IDENTITY INFORMATION	
1.5	**QUANTITY**	
1.7	**USE PATTERN**	
1.9	**SOURCES AND LEVELS OF EXPOSURE**	
ISSUES FOR DISCUSSION (IDENTIFY, IF ANY)	SIDS testing required:	

SIDS SUMMARY

DATE:

CAS NO:		Information	OECD Study	GLP	Other Study	Estimation Method	Acceptable	SIDS Testing Required
STUDY		**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**
PHYSICAL-CHEMICAL DATA								
2.1	Melting Point							
2.2	Boiling Point							
2.3	Density							
2.4	Vapour Pressure							
2.5	Partition Coefficient							
2.6	Water Solubility							
	pH and pKa values							
2.12	Oxidation: Reduction potential							
OTHER P/C STUDIES RECEIVED								
ENVIRONMENTAL FATE and PATHWAY								
3.1.1	Photodegradation							
3.1.2	Stability in water							
3.2	Monitoring data							
3.3	Transport and Distribution							
3.5	Biodegradation							
OTHER ENV FATE STUDIES RECEIVED								
ECOTOXICITY								
4.1	Acute toxicity to Fish							
4.2	Acute toxicity to Daphnia							
4.3	Toxicity to Algae							
4.5.2	Chronic toxicity to Daphnia							
4.6.1	Toxicity to Soil dwelling organisms							
4.6.2	Toxicity to Terrestrial plants							
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TOXICITY								
5.1.1	Acute Oral							
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5.1.3	Acute Dermal							
5.4	Repeated Dose							
5.5	Genetic Toxicity *in vitro*							
	. Gene mutation							
	. Chromosomal aberration							
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5.9	Development / Teratogenicity							
5.11	Human experience							
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1. GENERAL INFORMATION

1.01 SUBSTANCE INFORMATION

***A. Cast number** . . . . . -. . . . . -. . . . . .

B. Name *(IUPAC name)* .....

***C. Name** *(OECD name)* .....

†D. CAS Descriptor *(where applicable for complex chemicals)*

.....

E. EINECS-Number . . . . . -. . . . . -. . . . . .

F. Molecular Formula .....

***G. Structural Formula** *(indicate the structural formula in smiles code, if available)*

.....

H. Substance Group *(if possible, only for petroleum products, see HEDSET explanatory note)*

.....

I. Substance Remark *(Indicate the substance remark as prescribed in the EINECS Inventory, if possible)*

.....

J. Molecular Weight .....

1.02 OECD INFORMATION

A. Sponsor Country: .....

B. Lead Organisation:

Name of Lead Organisation: .....
Contact person:.....
Address:
Street: .....
Postal code: .....
Town: .....
Country:.....
Tel: .....
Fax: .....

C. **Name of responder** *(Information on a responder should be provided when companies respond to Lead Organisation or SIDS Contact Points.)*

Name:.....
Address:.....
Street:.....
Postal code:.....
Town:.....
Country:.....
Tel:.....
Fax:.....

1.1 GENERAL SUBSTANCE INFORMATION

A. Type of Substance

element [ ]; inorganic [ ]; natural substance [ ]; organic [ ]; organometallic [ ];
petroleum product [ ]

B. Physical State *(at 20°C and 1.013 hPa)*

gaseous [ ]; liquid [ ]; solid **[ ]**

C. Purity *(indicate the percentage by weight/weight)*.....

1.2 SYNONYMS .....
.....
.....
.....
.....

1.3 IMPURITIES *[Indicate CAS No., chemical name (IUPAC name is preferable), percentage, if possible EINECS number.]*

CAS No: . . . . . - . . . . . - . . . . .
EINECS No: .....
Name: .....
Value: .....
Remarks: .....

1.4 ADDITIVES *(e.g. stabilising agents, inhibitors etc. Indicate CAS No., chemical name (IUPAC name is preferable), percentage, if possible EINECS number), the component of the UVCB (substance with no defined composition) should be indicated here.*)

CAS No: . . . . . - . . . . . - . . . . .
EINECS No: . . . . . - . . . . . - . . . . .
Name: .....
Value: .....
Remarks: .....

***1.5 QUANTITY** *[Information on production or import levels should be provided in figures or ranges (e.g. 1,000-5,000, 5,000-10,000 tonnes, etc.) per responder or country and the date for which those ranges apply should be given. For EU Member states, only indicate the EU import figure. Give an estimation of the global production quantity in the remarks field. Information on the number of producers in the country and the source of information should also be given in the remarks field.)*

Remarks: *(If possible, indicate if the substance was produced and/or imported during the 12 months following adoption of the EU regulation on existing chemicals.)* .....
.....
.....
Reference: .....

1.6 LABELLING AND CLASSIFICATION *[If possible, enter information on labelling and classification, such as labelling and classification system, existence of specific limit, symbols, nota, R-Phrases and S-Phrases of EC Directive 67/548/EEC. See HEDSET Explanatory Note.]*

Labelling
Type: .....
Specific limits: .....
Symbols: .....
Nota: .....

R-phrases: .....
S-phrases: .....
Text of S-phrases: .....
Remarks: .....

Classification
Type: .....
Category of danger: .....
R-phrases: .....
Remarks: .....

***1.7 USE PATTERN**

A. General *[Data on use pattern have to be given by assigning main types according to their exposure relevance (i.e. non-dispersive use, use in closed systems, use resulting in inclusion into or onto matrix and wide dispersive use), industrial categories (e.g. basic chemical industry, chemical industry, agricultural industry, personal and domestic use) and use categories such as colouring agents, intermediates, solvents, adhesives, cleaning/washing agents, fertilisers, impregnation agents, surface-active, etc. If available, give an estimation of different uses in percentage terms.]*

	Type of Use:		**Category:**
	(a)	main industrial use	.....
	(b)	main industrial use	.....
Remarks:	(a)		.....
	(b)		.....
Reference:			.....

B. **Uses in Consumer Products** *[If the chemical is present in consumer products as marketed, give details of products' function (e.g. detergent, etc.), and percentage in product and physical state of product as marketed (e.g. aerosol, powder or liquid)]*

Function	Amount present	Physical state
.....	.....	.....

Remarks: . .....
Reference: . .....

1.8 **OCCUPATIONAL EXPOSURE LIMIT VALUE** *(Indicate the type of occupational exposure limit value including short-term exposure limit value. If a value does not exist, give the hygiene standard of the producer company if available. See also 5.11.)*

Exposure limit value
Type: .....
Value: .....

Short term exposure limit value
Value: .....
Length of exposure period:. .....
Frequency: .....
Remarks: .....
Reference: .....

*** 1.9** **SOURCES OF EXPOSURE**

Describe sources of potential human [other than concentration of chemicals in the workplace and indoor environment (see 5.11)], or environmental exposure, including emission data (e.g. quantities per media with information such as time dimensions of release, indication of type of release (e.g. point source or diffuse), type of estimating (e.g. average or worst case), uncertainties in estimation), for all phases of the life cycle of the chemical, if available, including manufacturing and user areas.

For environmental exposure, indicate the production process briefly, number of sites of manufacture and, the basis for concluding that the process is "closed" if applicable.

Also an indication of measured exposure levels (expressed in an appropriate form, e.g. geometric mean and standard deviation) can be mentioned here. Any information that will help to focus the assessment of exposure (either quantitative or quantitative in nature) can be mentioned, if available.)

Source: Media of release:. .....
Quantities per media:. .....
Remarks: .....
Reference: .....

1.10 ADDITIONAL REMARKS

A. Options for disposal *[Mode of disposal (e.g. incineration, release to sewage system, etc.) for each category and type of use, if appropriate; recycling possibility]*

Remarks: .....
Reference: .....

B. Other remarks

Remarks: .....
Reference: .....

2. PHYSICAL-CHEMICAL DATA

***2.1 MELTING POINT** *(If more than one, identify the recommended value.)*

Value: . . . . . °C
Decomposition: Yes **[ ]** No **[ ]** Ambiguous **[ ]**
Sublimation: Yes **[ ]** No **[ ]** Ambiguous **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updated of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

***2.2 BOILING POINT** *(If more than one, identify the recommended value.)*

Value: . . . . . °C
Pressure: at . . . . . hPa
Decomposition: Yes **[ ]** No **[ ]** Ambiguous **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

†2.3 DENSITY (relative density) *(Where applicable, indicate the relative density of the substance.)*

Type: Bulk density **[ ]**; Density **[ ]**; Relative Density **[ ]**
Value: .....
Temperature: . . . . . °C
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

***2.4 VAPOUR PRESSURE** *(if more than one, identify the recommended value)*

Value: . . . . . hPa
Temperature: . . . . . °C
Method: calculated **[ ]**; measured **[ ]**
[e.g. OECD, other (with the year of publication or updated of the method used)].
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**

Remarks: .....
Reference: .....

***2.5 PARTITION COEFFICIENT $log_{10}P_{ow}$** *(if more than one, identify the recommended value)*

Log Pow: . . . . . .
Temperature: . . . . . °C
Method: calculated **[ ]**; measured **[ ]**
[e.g. OECD, other (with the year of publication or updating of the ..... method used)].
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

***2.6 WATER SOLUBILITY** *(if more than one, identify the recommended value)*

A. Solubility

Value: . . . . . .
Temperature: . . . . . °C
Description: Miscible **[ ]**; Of very high solubility **[ ]**;
Of high solubility **[ ]**; Soluble **[ ]**; Slightly soluble **[ ]**;
Of low solubility **[ ]**; Of very low solubility **[ ]**; Not soluble **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

B. pH Value, pKa Value

pH Value: . . . . . .
Concentration: . . . . . .
Temperature: . . . . . °C
Method: *[e.g. OECD, other (with the year of publication or updating of the method used).*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
(Where applicable, enter values for the dissociation constant(s) and the conditions under which they were measured.)
pKa value . . . . . at 25°C
Remarks: .....
Reference: .....

2.7 FLASH POINT *(liquids)*

Value: . . . . . °C
Type of test: Closed cup **[ ]**; Open cup **[ ]**; Other **[ ]**
Method: *(with the year of publication or updating of the method used).* .....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

2.8 AUTO FLAMMABILITY *(solid/gases)*

Value: . . . . . °C
Pressure: . . . . . hPa
Method: *(with the year of publication or updating of the method used).* .....

. .....

GLP: Yes **[ ]** No **[ ]** ? **[ ]**

Remarks: . .....

Reference: . .....

2.9 FLAMMABILITY

Results: Extremely flammable **[ ]**; Extremely flammable - liquified gas **[ ]**;
Highly Flammable **[ ]**; Flammable **[ ]**; Non flammable **[ ]**;
Spontaneously flammable in air **[ ]**; Contact with water liberates highly flammable gases **[ ]**; Other **[ ]**

Method: *(with the year of publication or updating of the method used).* .....
. .....

GLP: Yes **[ ]** No **[ ]** ? **[ ]**

Remarks: . .....

Reference: . .....

2.10 EXPLOSIVE PROPERTIES

Results: Explosive under influence of a flame**[ ]**;
More sensitive to friction than m-dinitrobenzene **[ ]**;
More sensitive to shock than m-dinitrobenzene **[ ]**; Not explosive **[ ]**;
Other **[ ]**

Method: *(with the year of publication or updating of the method used).* .....
. .....

GLP: Yes **[ ]** No **[ ]** ? **[ ]**

Remarks: . .....

Reference: . .....

2.11 OXIDISING PROPERTIES

Results: Maximum burning rate equal or higher than reference mixture **[ ]**;
Vigorous reaction in preliminary test **[ ]**;
No oxidising properties **[ ]**; Other **[ ]**

Method: *(with the year of publication or updating of the method used).* .....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

†2.12 OXIDATION: REDUCTION POTENTIAL

(Where applicable, indicate the redox potential and the conditions under which it was measured.)

Value: . . . . . mV
Method: *(with the year of publication or updating of the method used)*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

2.13 ADDITIONAL DATA

A. Partition co-efficient between soil/sediment and water (Kd)

Value: . . . . . .
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Remarks: .....
Reference: .....

B. Other data

(e.g. Henry's Law constant, fat solubility, surface tension (of aqueous solution), adsorption/desorption on soil, particle size distribution, etc.)

Results: .....
Remarks: .....
Reference: .....

3. ENVIRONMENTAL FATE AND PATHWAYS

[Reporting of studies should give the test method, test conditions (laboratory versus field studies), test results (e.g. % degradation in specified time period) and reference. Information on breakdown products (transient and stable) should be provided when available.]

3.1 STABILITY

*3.1.1 PHOTODEGRADATION

Type: Air **[ ]**; Water **[ ]**; Soil **[ ]**; Other **[ ]**
Light source: Sunlight **[ ]**; Xenon lamp **[ ]**; Other **[ ]**
Light spectrum: . . . . . nm
Relative intensity: . . . . . *(based on intensity of sunlight)*
Spectrum of substance: *[e.g. lambda (max.)(>295nm) and epsilon (max) or epsilon (295nm)]*
. . . . . nm
Concentration of Substance: . . . . . .
Temperature: . . . . . °C
Direct photolysis:
Half life: . . . . . .
Degradation: . . . . . % (weight/weight) after . . . . . (exposure time)
Quantum yield: . . . . . .
Indirect Photolysis:
Type of sensitizer: . . . . . .
Concentration of sensitizer: . . . . . .
Rate constant (radical): . . . . . cm^3/molecule*sec
Degradation: . . . . . .
Method: calculated **[ ]**; measured **[ ]**
[e.g. OECD, other (with the year of publication or updating of the method used)]
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity:. . . . . .
Remarks: .....
Reference: .....

*3.1.2 STABILITY IN WATER

Type: Abiotic (hydrolysis) **[ ]**; biotic (sediment)**[ ]**
Half life: . . . . . at pH . . . . . at . . . . . °C
Degradation: . . . . . at pH . . . . . at . . . . . °C after
. . . . . (exposure time)
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]* .....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: *(e.g. CAS number, name and percentage of degradation products)*
.....
Reference: .....

3.1.3 STABILITY IN SOIL

Type : Field trial **[ ]**; Laboratory **[ ]**; Other **[ ]**
Radiolabel: Yes **[ ]** No **[ ]** ? **[ ]**
Concentration: . . . . . .
Soil temperature: . . . . . °C
Soil humidity: . . . . . .
Soil classification: DIN19863 **[ ]**; NF X31-107 **[ ]**; USDA **[ ]**; Other **[ ]**
year . . . . . .
Content of clay etc.: Clay . . . . . %, Silt . . . . . %, Sand . . . . . %
Organic Carbon: . . . . . .
Soil pH: . . . . . .
Cation exchange capacity: . . . . . .
Microbial biomass: . . . . . .
Dissipation time: DT 50 : . . . . . .
DT 90 : . . . . . .
Dissipation : . . . . . % after . . . . . (time)
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

*3.2 MONITORING DATA (ENVIRONMENTAL)

Note that data on biological effects monitoring, including biomagnification, and biotransformation and kinetics in environmental species are to be reported in section 4.7 and 4.8, respectively. Nonetheless, concentration in various biota should be reported here. Data on concentration in the workplace or indoor environment should be reported under item 5.11.

Type of Measurement: Background **[ ]**; At contaminated site **[ ]**; Other **[ ]**
Media: .....
Results: .....
Remarks: .....
Reference: .....

3.3 TRANSPORT AND DISTRIBUTION BETWEEN ENVIRONMENTAL COMPARTMENTS INCLUDING ESTIMATED ENVIRONMENTAL CONCENTRATIONS AND DISTRIBUTION PATHWAYS *(e.g. during the chemical life-cycle. The information should indicate whether the calculation is on a global basis or is site-specific, and whether it is based on laboratory measurements or field observations.)*

***3.3.1 TRANSPORT**

Type: Adsorption **[ ]**; Desorption **[ ]**; Volatility **[ ]**; Other **[ ]**
Media: . .....
Method: . .....
Results: . .....
Remarks: . .....
Reference: . .....

***3.3.2 THEORETICAL DISTRIBUTION (FUGACITY CALCULATION)**

Media: Air-biota **[ ]**; Air-biota-sediment-soil-water **[ ]**; Soil-biota **[ ]**; Water-air **[ ]**; Water-biota **[ ]**; Water-soil **[ ]**; Other **[ ]**
Method: Fugacity level I **[ ]**; Fugacity level II **[ ]**; Fugacity level III **[ ]**; Fugacity level IV **[ ]**; Other (calculation) **[ ]**; Other (measurement)**[ ]**
. .....
Results: . .....
Remarks: . .....
Reference: . .....

3.4 IDENTIFICATION OF MAIN MODE OF DEGRADABILITY IN ACTUAL USE

Results: . .....
Remarks: . .....
Reference: . .....

***3.5 BIODEGRADATION**

Type: aerobic **[ ]**; anaerobic **[ ]**
Inoculum: adapted **[ ]**; non-adapted **[ ]**; .....
Concentration of the chemical: . . . . . related to COD **[ ]**; DOC **[ ]**; test substance **[ ]**
Medium: water **[ ];** water-sediment **[ ];** soil **[ ];** sewage treatment **[ ]**
Degradation: *(percentage reduction/exposure time)*
. . . . . % after . . . . . (time)
Results: *(see OECD Guidelines)* readily biodeg. **[ ];** inherently biodeg. **[ ]**; under test condition no biodegradation observed **[ ]**, other **[ ]**
Kinetic (e.g. Zahn-Wellens-Test) . . . . . % in . . . . . (time)
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
. .....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: *[In the case of poorly soluble chemicals, treatment given (nature, concentration, CAS number, name and percentage of degradation products etc.)]:* . .....
. .....
Reference: . .....

3.6 BOD_5, COD OR RATIO BOD_5/COD

BOD_5
Method: . . . . . .
Concentration: . . . . . related to COD **[ ]**; DOC **[ ]**; Test substance **[ ]**
Value: . . . . . mg O_2/l
GLP: Yes **[ ]** No **[ ]** ? **[ ]**

COD
Method: . . . . . .
Value: . . . . . mg O_2/g
GLP: Yes **[ ]** No **[ ]** ? **[ ]**

Ratio BOD_5/COD: . . . . . .
Remarks: .....
Reference: .....

3.7 BIOACCUMULATION

Species: .....
Exposure period: .....
Temperature: . . . . . °C
Concentration: . . . . . .
BCF: . . . . . .
Elimination: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
Type of test: calculated **[ ]**; measured **[ ]**
static **[ ]**; semi-static **[ ]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity:. . . . . .
Remarks: .....
Reference: .....

3.8 ADDITIONAL REMARKS

A. Sewage treatment *(information on treatability of the substance)*

Results: .....
Remarks: .....
Reference: .....

B. Other information *[information that will help to focus the exposure assessment (either qualitative or quantitative)]*

Results: .....
Remarks: .....
Reference: .....

4. ECOTOXICITY

*4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type of test: static **[ ]**; semi-static **[ ]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**
open-system **[ ]**; closed-system **[ ]**
Species: .....
Exposure period: .....
Results: LC_{50} (24h) = ... mg/l
LC_{50} (48h) = ... mg/l
LC_{50} (72h) = ... mg/l
LC_{50} (96h) = ... mg/l
NOEC = ... mg/l
LOEC = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

*A. Daphnia

Type of test: static **[ ]**; semi-static **[ ]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**;
open-system **[ ]**; closed-system **[ ]**
Species: .....
Exposure period: .....
Results: EC_{50} (24h) = ... mg/l
EC_{50} (48h) = ... mg/l
EC_{xx} (..h) = ... mg/l
NOEC = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

B. Other aquatic organisms

Type of test: static **[ ]**; semi-static **[ ]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**; open-system **[ ]**;
closed-system **[ ]**
Species: .....
Exposure period: .....
Results: EC_{50} (24h) = ... mg/l
EC_{50} (48h) = ... mg/l
EC_{xx} (..h) = ... mg/l
NOEC = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .

Remarks: .....
Reference: .....

***4.3 TOXICITY TO AQUATIC PLANTS, e.g. algae**

Species: .....
Endpoint: Biomass **[ ]**; Growth rate **[ ]**; Other **[ ]**
Exposure period: .....
Results: . . . . . EC_{50} (. . . . . .h) = ... mg/l
(Endpoint) EC_{xx} (. . . . . .h) = ... mg/l
NOEC = ... mg/l
LOEC = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
open-system **[ ]**; closed-system **[ ]**
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

4.4 TOXICITY TO BACTERIA *(Single species tests and tests on overall processes such as nitrification or soil respiration are included in this item.)*

Type: Aquatic **[ ]**; Field **[ ]**; Soil **[ ]**; Other **[ ]**
Species: .....
Exposure Period: .....
Results: EC_{50} (. . . h) = ... mg/l
EC_{xx} (. . . h) = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

4.5 CHRONIC TOXICITY TO AQUATIC ORGANISMS

4.5.1 CHRONIC TOXICITY TO FISH (*effects on reproduction, embryo/larva, etc.*)

Type of test: static **[ ]**; semi-static **[ ]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**; open-system **[ ]**; closed-system **[ ]**
Species: .....
Endpoint: Length of fish **[ ]**; Weight of fish **[ ]**;
Reproduction rate **[ ]**; Other **[ ]**
Exposure period: .....
Results: . . . . . EC_{50} (..d) = ... mg/l
(Endpoint) EC_{xx} (..d) = ... mg/l
NOEC = ...mg/l
LOEC = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....

Reference: .....

(*)4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES *(e.g. daphnia reproduction. The need to conduct tests for this endpoint will depend ~~inter alia~~ upon possible concern for long term effects.)*

Type of test: static **[ ]**; semi-static **[ ]**; flow-through **[ ]**; other *(e.g. field test)* **[ ]**; open-system **[ ]**; closed-system **[ ]**
Species: .....
Endpoint: Mortality **[ ]**; Reproduction rate **[ ]**; Other **[ ]**
Exposure period: . . . . . .
Results: . . . . . EC_{50} (. . . . . h) = ... mg/l
(Endpoint) EC_{xx} (. . . . . d) = ... mg/l
NOEC = ... mg/l
LOEC = ... mg/l
Analytical monitoring: Yes **[ ]** No **[ ]** ? **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

Type : Artificial soil **[ ]**; Filter paper **[ ]**; Other **[ ]**
Species: .....
Endpoint: Mortality **[ ]**; Weight **[ ]**; Other **[ ]**
Exposure period: .....
Results: . . . . . EC_{50} (. . . . . d) = ... mg/kg
(Endpoint) EC_{50} (. . . . . d) = ... mg/kg
EC_{xx} (. . . . . d) = ... mg/kg
NOEC = ... mg/kg
LOEC = ... mg/kg
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)].*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

(a)
Species: .....
Endpoint: Emergence **[ ]**; Growth **[ ]**; Other **[ ]**
Exposure period: .....
Results: EC_{50} and/or LC_{50} (7d) = ... mg/l
EC_{50} and/or LC_{50}(14d) = ... mg/l
EC_{xx} and/or LC_{xx} (xxd) = ...mg/l
NOEC = ...mg/l
LOEC = ...mg/l
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

(b)
Species: .....
Endpoint: Emergence **[ ]**; Growth **[ ]**; Other **[ ]**
Exposure period: .....
Results: EC_{50} and/or LC_{50} (7d) = ... mg/l
EC_{50} and/or LC_{50}(14d) = ... mg/l
EC_{xx} and/or LC_{xx} (xxd) = ...mg/l
NOEC = ...mg/l
LOEC = ...mg/l
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

(c)
Species: .....
Endpoint: Emergence **[ ]**; Growth **[ ]**; Other **[ ]**
Exposure period: .....

Results: EC_{50} and/or LC_{50} (7d) = ... mg/l
EC_{50} and/or LC_{50}(14d) = ... mg/l
EC_{xx} and/or LC_{xx} (xxd) = ...mg/l
NOEC = ...mg/l
LOEC = ...mg/l
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

4.6.3 TOXICITY TO OTHER NON MAMMALIAN TERRESTRIAL SPECIES (INCLUDING AVIAN)

Species: .....
Endpoint: Mortality **[ ]**; Reproduction rate **[ ]**; Weight **[ ]**; Other **[ ]**
Exposure period: .....
Results: LD_{xx} or LC_{xx} (xxd) = ... mg/kg
NOEC = ... mg/kg
LOEC = ... mg/kg
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*

GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: ....., purity: .....
Remarks: .....
Reference: .....

4.7 BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION)

(Studies on variation of predominant species in certain ecosystems (e.g. mesocosm) and monitoring of biological effects are included.)

Results: Substance:.....
Species or ecosystem studied:.....
Effects monitored: .....
Results:.....
Chemical analysis:.....
Remarks: *(Information on environmental conditions (e.g. water characteristics: suspended matter, pH, temperature, hardness; soil/sediment characteristics: % organic matter, clay content)*
.....
Reference: .....

4.8 BIOTRANSFORMATION AND KINETICS

(Under this item, studies on absorption, distribution, metabolism and excretion etc. should be given.)

Type: Animal **[ ]**; Aquatic **[ ]**; Plant **[ ]**; Terrestrial **[ ]**; Other **[ ]**
Results: .....
Remarks: .....
Reference: .....

4.9 ADDITIONAL REMARKS

Results: .....
Remarks: .....
Reference: .....

5. TOXICITY

(Where observations on humans are available, these should be entered in the appropriate "Comments" section or under section 5.11.)

*5.1 ACUTE TOXICITY

5.1.1 ACUTE ORAL TOXICITY

Type: LD_0 [ ]; LD_{100} [ ]; LD_{50} [ ]; LDL_0 [ ]; Other [ ]
Species/strain: .....
Value: . . . . . mg/kg b.w.:
Discriminating dose: .....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes [ ] No [ ] ? [ ]
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.1.2 ACUTE INHALATION TOXICITY

Type: LC_0 [ ]; LC_{100} [ ]; LC_{50} [ ]; LCL_0 [ ]; Other [ ]
Species/strain: .....
Exposure time: .....
Value: .....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes [ ] No [ ] ? [ ]
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.1.3 ACUTE DERMAL TOXICITY

Type: LD_0 [ ]; LD_{100} [ ]; LD_{50} [ ]; LDL_0 [ ]; Other [ ]
Species/strain: .....
Value: . . . . . mg/kg b.w.
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes [ ] No [ ] ? [ ]
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.1.4 ACUTE TOXICITY, OTHER ROUTES OF ADMINISTRATION
(e.g. subcutaneous, intravenous, etc.)

Type: LC_0 **[ ]**; LC_{100} **[ ]**; LC_{50} **[ ]**; LCL_0 **[ ]**; Other **[ ]**
LD_0 **[ ]**; LD_{100} **[ ]**; LD_{50} **[ ]**; LDL_0 **[ ]**; Other **[ ]**
Species/strain: .....
Route of Administration: i.m. **[ ]**; i.p. **[ ]**; i.v. **[ ]**; infusion **[ ]**; s.c. **[ ]**; other **[ ]**
Exposure time: .....
Value: .....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION

Species/strain: .....
Results: Highly corrosive **[ ]**; Corrosive **[ ]**; Highly irritating **[ ]**;
Irritating **[ ]**; Moderate irritating **[ ]**; Slightly irritating **[ ]**;
Not irritating **[ ]**
Classification: *(If possible, according to EC Directive 67/548/EEC)*
Highly corrosive (causes severe burns) **[ ]**;
Corrosive (causes burns) **[ ]**; Irritating **[ ]**; Not irritating **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.2.2 EYE IRRITATION/CORROSION

Species/strain: .....
Results: Highly corrosive **[ ]**; Corrosive **[ ]**; Highly irritating **[ ]**;
Irritating **[ ]**; Moderate irritating **[ ]**; Slightly irritating **[ ]**;
Not irritating **[ ]**
Classification: *(if possible, according to EC Directive 67/548/EEC)*
Irritating **[ ]**; Not irritating **[ ]**; Risk of serious damage to eyes **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.3 SKIN SENSITISATION

Type: .....
Species/strain: .....
Results: Sensitizing **[ ]**; Not sensitizing **[ ]**; Ambiguous **[ ]**
Classification: *(if possible, according to EC Directive 67/548/EEC)*
Sensitizing **[ ]**; Not sensitizing **[ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .

Remarks: .....
Reference: .....

***5.4 REPEATED DOSE TOXICITY**

Species/strain: .....
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[ ]**
Route of Administration: .....
Exposure period: .....
Frequency of treatment: .....
Post exposure observation period: . .....
Dose: .....
Control group: Yes **[ ]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
NOEL: .....
LOEL: .....
Results: .....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Reference: .....

***5.5 GENETIC TOXICITY IN VITRO**

A. BACTERIAL TEST

Type: *(e.g. Bacterial reverse mutation assay, Bacterial gene mutation study, Cytogenetic Assay etc.)*.....
.....
System of testing: .....
Concentration: .....
Metabolic activation: With **[ ]**; Without **[ ]**; With and Without **[ ]**; No data **[ ]**
Results:
Cytotoxicity conc: With metabolic activation:.....
Without metabolic activation:.....
Precipitation conc: .....
Genotoxic effects: + ? -
With metabolic activation: **[ ] [ ] [ ]**
Without metabolic activation: **[ ] [ ] [ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: ....., purity: .....
Remarks: .....
Reference: .....

B. NON-BACTERIAL IN VITRO TEST

Type: *(e.g. mammalian cell gene mutation assay, cytogenetic assay, etc.)*
.....
System of testing: .....
Concentration: .....
Metabolic activation: With **[ ]**; Without **[ ]**; With and Without **[ ]**; No data **[ ]**
Results:
Cytotoxicity conc: With metabolic activation:.....
Without metabolic activation:.....

Precipitation conc: .....
Genotoxic effects: + ? -
With metabolic activation: **[ ] [ ] [ ]**
Without metabolic activation: **[ ] [ ] [ ]**
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

*** 5.6 GENETIC TOXICITY IN VIVO**

Type: *(e.g. micronucleus assay, etc.)*
.....
Species/strain: .....
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[ ]**
Route of Administration: .....
Exposure period: .....
Doses: .....
Results:
Effect on mitotic
index or P/N ratio: .....
Genotoxic effects: + ? -
[ ] [ ] [ ]
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.7 CARCINOGENICITY

Species/strain: .....
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[ ]**
Route of Administration: .....
Exposure period: .....
Frequency of treatment: .....
Postexposure observation period: .....
Doses: .....
Control group: Yes **[ ]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
Results: .....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

***5.8 TOXICITY TO REPRODUCTION**

Type: Fertility **[ ]**; One-generation study **[ ]**; Two-generation study **[ ]**;
Other **[ ]**
Species/strain: .....
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[ ]**

Route of Administration:.....
Exposure period: .....
Frequency of treatment:.....
Post exposure observation period: .....
Premating exposure period: male: . . . . . , female: .....
Duration of the test: .....
Doses: .....
Control group: Yes **[ ]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
NOEL Parental: .....
NOEL F1 Offspring: .....
NOEL F2 Offspring: .....
Results: .....
General parental toxicity:.....
Toxicity to offspring: *(weights of litter, postnatal growth, viability, etc.)*
.....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

*5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

Species/strain: .....
Sex: Female **[ ]**; Male **[ ]**; Male/Female **[ ]**; No data **[ ]**
Route of Administration: .....
Duration of the test: .....
Exposure period: .....
Frequency of treatment: .....
Doses: .....
Control group: Yes **[ ]**; No **[ ]**; No data **[ ]**;
Concurrent no treatment **[ ]**; Concurrent vehicle **[ ]**; Historical **[ ]**
NOEL Maternal Toxicity: .....
NOEL teratogenicity : .....
Results: .....
Maternal general toxicity: .....
Pregnancy/litter data: .....
Foetal data: .....
Method: *[e.g. OECD, other (with the year of publication or updating of the method used)]*.....
.....
GLP: Yes **[ ]** No **[ ]** ? **[ ]**
Test substance: . . . . . , purity: . . . . . .
Remarks: .....
Reference: .....

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

Type: *(e.g. neurotoxicity, immunotoxicity, etc.)*
.....
Results: .....
Remarks: .....
Reference: .....

B. Toxicodynamics, toxicokinetics

Type: *(e.g. toxicodynamics, toxicokinetics)*
. .....
Results: . .....
Remarks: . .....
References: . .....

*** 5.11 EXPERIENCE WITH HUMAN EXPOSURE**

(Describe information on workplace exposure such as concentration of chemicals in the workplace or indoor environment (manufacturing, maintenance and professional use), number of workers (in ranges for each situation), frequency and duration of exposure, if available. In addition, enter details of effects of accidental or occupational exposure, epidemiological and clinical studies, case reports, etc.)

Results: . .....
Remarks: . .....
Reference: . .....

6. REFERENCES

(Indicate the name of the book, journal, etc. where the study appears; volume; page numbers; and date of report or publication. In general, information should be taken from primary sources and quoting from secondary references such as a review article should be avoided. Where appropriate, indicate "unpublished report", its authors and their affiliation.)

2.5 Guidance for collection and transmission of exposure information for SIDS Initial Assessment

Introduction

1. Countries participating in the OECD Existing Chemicals Programme (i.e. SIDS Programme) are requested to collect a set of exposure data on High Production Volume (HPV) chemicals for their initial assessment. These data will be used to assess potential exposures to the chemical.

2. In order to collect exposure information in an effective and efficient way, the Steering Group on Existing Chemicals agreed at its meeting in November 1996 on a two-step approach for collection of exposure information. The OECD Secretariat has developed a format to be used for gathering exposure information based on the recommendations of the Steering Group. Guidance for collection and transmission of exposure information is summarised below. The discussions at the Task Force Meeting held in Dortmund, Germany, in June 1995, and the experiences gained later on are also taken into account.

First Step

3. Beginning with Phase 5 chemicals, the Secretariat informs Member countries which chemicals are being sponsored and requests them to collect exposure information on these chemicals, i.e. at the information gathering stage. Beginning with Phase 6, information giving the rationale for the selection of each chemical has been provided for Member countries to easily focus on specific exposure situations. The list of producing countries could also be attached.

4. Member countries gather easily-available exposure information on the elements in the following list on all the chemicals at this stage and forward it to the relevant Sponsor countries within 6 months. Items to be gathered can be selected by each Member country depending on the situation, but reasonable efforts should be made to collect the information.

- Produced, imported or used?
- Quantity (production, import and/or export volume)
- General information on use pattern
- MAK or equivalent occupational standards
- Information on classification and labelling
- National regulatory standards or other measures for management of exposure
- Other information (e.g. results of workplace monitoring, other information on occupational exposure, information on release to the environment, results of environmental monitoring, information on consumer exposure, safe handling procedures, etc.)

5. A form to be used for this purpose has been developed (see Annex 1 to this Section). This is also available on diskette. Member countries can modify it as appropriate. Member countries are expected to forward the collected information to the relevant Sponsor countries, with a copy to the Secretariat.

6. Sponsor countries gather more detailed national exposure information on their own sponsored chemicals. Examples of the items to be collected are shown in Annexes 2 and 3 to this Section, which were included in the recommendations by the Task Force Meeting. An example of a form to be used for collecting such information is shown in Annex 4 to this Section. Member countries can use it when they collect information from industry, modifying it as appropriate. They can also use it when they summarise data to forward to the appropriate Sponsor countries.

Second step

7. The second step of information gathering focuses on specific chemicals, especially those for which a potential hazard has been identified, normally at a SIDS Initial Assessment Meeting (SIAM).

8. Once it has been agreed at a SIAM that more detailed information on general or specific exposure information (e.g. occupational exposure, environmental release) be collected for certain chemicals, all Member countries are requested to collect such information. This procedure started with the chemicals identified at SIAM4 held in May 1996.

9. The form shown in Annex 4 to this Manual can be used, modified as appropriate.

10. If Sponsor countries feel that specific international exposure information is needed for the initial assessment of their sponsored chemicals, they can request other countries to collect it before developing an assessment report. In this case, the rationale for the request should be clarified.

General instructions on data collection

11. At the first step, non-Sponsor countries are expected to collect easily-available information. This can be done by using governmental databases (e.g. Product Register, Release Inventory), literature and/or a simple request to industry. Sponsor countries, on the other hand, are expected to collect more detailed information in co-operation with industry. At the second step, every Member country needs to work with industry as well.

12. It is recommended that Sponsor countries use the EXICHEM database as a starting place to find out which other Member countries or international organisations are collecting or analysing exposure information on the sponsored chemicals.

13. Industry's co-operation on collection of exposure information is voluntary in the OECD Existing Chemicals Programme, and should be based on readily available data and responsible estimates. However, it is recommended that the industry which produces a chemical make reasonable efforts to provide exposure and release information relating to manufacture and uses of that chemical. Co-operation and good communication between government and industry is very important when gathering exposure information.

14. An example of procedure for gathering and documenting use-related exposure information is given in Annex 5 to this Section. As shown there, it is important to record the efforts taken including negative results in order to avoid duplication of efforts.

15. As these data will be used for the initial assessment, ranges for numerical values are acceptable, especially in the first step (see the example of production volume in Annex 6 to this Section).

16. If any data are confidential, ranges or generic descriptions should be used to provide as much non-confidential data as possible. Any confidential data can be attached as an Annex. They will be made available for review only on a confidential basis, i.e. the conditions set out in the OECD Council Act concerning Exchange of Confidential Data on Chemicals [C(83)97(Final)] apply to the experts in each country that receives the data.

17. It is recommended that all information be provided in English to the relevant Sponsor countries.

18. As the formats for collection and transmission of exposure information are provided in a diskette as a part of this SIDS Manual (Word 6.0 for Windows), space and style can be modified as appropriate.

19. A brief overview of the exposure situation across the OECD should be prepared by the Sponsor country in a SIDS Initial Assessment Report (SIAR). The SIDS Dossier and SIAR for a given chemical should be made available to those interested parties who submitted data.

Specific instructions for the collection of detailed data

20. In order to evaluate the quality of data, it is important to distinguish "on-site" data mainly related to production and "off-site" data mainly related to downstream uses. The latter is also important in order to analyse the complete life

cycle of the chemical; however, it should be noted that such data concerning downstream use is usually derived based on estimation.

21. Release in a reasonable worst-case should be described.

22. With respect to occupational exposure, it is also important to distinguish exposure during manufacturing from that during occupational/professional use.

23. With respect to industry categories and use categories, it is recommended to use the categories in HEDSET (see Annex 6 to this Section).

24. Monitoring data are preferable for exposure assessment; however, representativeness should be reviewed. For validation of monitoring data, it is important to give some indication of the sampling and analytical methods. As space in the format is limited, detailed results can be attached to the format, as appropriate.

25 With respect to off-site release to the environment, it should be noted that small scale industry, consumer end-use of the chemicals or waste disposal where a chemical is likely to be available for environmental and human exposure should be considered. Examples of end-use categories are:

- cosmetics and toiletries
- soaps and detergents
- polishes and sanitation goods
- paints and coatings
- adhesives and sealants
- automotive care products
- pesticides and lawn/garden products

26 Detailed instructions are also given in italics in the format.

Other

27. If relevant data are not available, default values will be used in preparation of the SIARs.

28. If the initial assessment identifies any concern for the environment and/or human health, more detailed information may be collected later, as appropriate, such as that collected in the EPA/CMA/SOCMA Project (see Annex 5 to this Manual).

Annex 1

Form for Gathering Easily-Available Exposure Information in Non-Sponsor Countries on the Chemicals at the Information Gathering Stage (Phase xx Chemicals)

- *Please collect ~~easily-available information~~. Items to be gathered can be selected by each Member country.*
- *This form can be used for data collection and transmission, modified as appropriate. This form is also available on diskette.*
- *Please send the collected information on each chemical ~~to the relevant Sponsor countries~~ within 6 months, with a copy to the Secretariat.*

CAS Number:	**Responding Country:**
Sponsor Country:	**Chemical Name:**

1. Produced, imported or used?

- Production/Import: ☐ Yes ☐ No ☐ Unknown
- Use: ☐ Yes ☐ No ☐ Unknown

2. Quantity *(tonnes/year, ranges are acceptable)* (Year:)

- Production (a)
- Import (b)
- Export (c)
- Total (a + b - c)

3. General Information on use pattern *(Please describe them.)*

- Is this chemical only used in closed systems? ☐ Yes ☐ No ☐ Unknown
- Is there any consumer use? ☐ Yes ☐ No ☐ Unknown

4. MAK or equivalent occupational standard *(mg/m^3 with time period)*

5. Information on classification and labelling *(Please describe them.)*

6. National regulatory standards *(purpose and value)* **or other measures for management of exposure**

References

CAS Number:	Responding Country:

7. Other information *(If some of the following information is available, please tick (✓) the items and describe data below or attach an additional paper, as appropriate.)*

- ☐ **Results of workplace monitoring**
- ☐ **Other information on occupational exposure**
- ☐ **Information on release to the environment**
- ☐ **Results of environmental monitoring**
- ☐ **Information on consumer exposure**
- ☐ **Safe handling procedure**
- ☐ **Other information (Please describe below.)**

References

Annex 2

Proposed Data Set on Environmental Exposure for the SIDS Initial Assessment[***]

Information included in the original SIDS elements

1. production volume (in each country and approximate OECD total, if possible)
2. use pattern including the approximate percentage of production volume in each use, if possible. [identify use categories (use a footnote or a table to indicate countries reporting the use)]

Basic information concerning release to the environment from point sources

3. national regulatory standards (e.g. effluent guidelines, water quality criteria)
4. release data to each environmental compartment (i.e. surface water, air, soil)
5. industry sectors (e.g. industrial categories in the HEDSET) in which the chemical is processed or used.
6. approximate number of sites per industry sector and total number of sites where chemical is manufactured, processed or used.
7. industrial processes associated with uses of the chemical which contain water as a reactant, solvent or by-product and hence have a likelihood of generating a surface water release.

Basic information concerning other releases to the environment (mainly to surface water)

8. consumer end-uses of the chemical or small scale industry where the chemical is likely to be available for ecological exposure. Examples of the end-use categories could be:

    - cosmetics and toiletries
    - soaps and detergents
    - polishes and sanitation goods
    - paints and coatings
    - adhesives and sealants
    - automotive care products
    - pesticides and lawn/garden products

    The weight percent of the chemical in each consumer end-use product should preferably be identified.

Others

9. Monitoring data of emissions of the chemical
10. Monitoring data of the chemical in the environment

[***] The data set shown in this Annex was proposed by the Task Force Meeting held in Dortmund, Germany, in June 1995 as an appropriate one for the SIDS Initial Assessment. After a pilot study, the Steering Group on Existing Chemicals thought that it might be difficult to ask all the Member countries to collect such information, but that the Sponsor countries should collect detailed information on their Sponsored chemicals.

Annex 3

Proposed Data Set on Human Exposure for the SIDS Initial Assessment[****]

A. CONSUMER EXPOSURE

In this area it is expected that little measured data would be available and that the assessor would rely on calculated data.

Basic Information

1. use pattern (The percentage or range of production volume in each of the use categories should be identified.)
2. weight fraction in product and dilution factor (before use) if available
3. form of product as marketed.

Others

4. frequency of use
5. duration of use
6. route and extent of exposure (oral, dermal, inhalation)
7. function of chemical in product

B. OCCUPATIONAL EXPOSURE

Basic Information

1. details of process or processes involved (e.g. continuous/batch, open/closed)
2. MAK or equivalent occupational standard
3. protective measures
   - engineering control
   - personal protection
4. use description and approximate exposure from non-manufacturing and professional use
5. use pattern

Others

6. Workplace monitoring data with details of statistical analysis and description of exposure scenarios
7. approximate number of sites per industry sector and total number of sites where chemical is manufactured, processed or used.
8. number of workers per site if available
9. frequency and duration of exposure
10. characteristics of exposed population

[****] The data set shown in this Annex was proposed by the Task Force Meeting held in Dortmund, Germany, in June 1995 as an appropriate one for the SIDS Initial Assessment. After a pilot study, the Steering Group on Existing Chemicals thought that it might be difficult to ask all the Member countries to collect such information, but that the Sponsor countries should collect detailed information on their Sponsored chemicals.

Annex 4

Proposed Format for Gathering More Detailed Exposure Information for SIDS Initial Assessment

- COVER PAGE -

A. IDENTITY OF RESPONDER

Name:
Company/Organisation:
Address/Country:

Tel:
Fax:
Date:

B: LIST OF CHEMICALS ON WHICH EXPOSURE INFORMATION HAS BEEN GATHERED *(Please tick the names of the chemicals for which exposure information is attached.)*

CAS No.	Chemical Name	CAS No.	Chemical Name
☐ xxxxx	xxxxxx	☐ xxxxx	xxxxxx
☐ xxxxx	xxxxxx	☐ xxxxx	xxxxxx

Other chemicals *(Please describe CAS No. and the name below.)*

General Instructions

The attached format, developed by the OECD Secretariat, is intended to be used for gathering more detailed exposure information on High Production Volume (HPV) chemicals in the OECD Existing Chemicals Programme. It is to be used by industry when submitting data to SIDS Contact Points. SIDS Contact Points can also use this format when summarising data to forward to the appropriate Sponsor countries, when necessary.

Completion of this form by each company is voluntary, and should be based on readily available data and responsible estimates. However, it is expected that all reasonable efforts will be made in gathering the necessary information.

As these data will be used for the initial assessment, ranges for numerical values are acceptable.

If any data are confidential, please use ranges or generic descriptions to provide as much non-confidential data as possible. Any confidential data could be attached as an Annex to this form. They will be made available for review only on a confidential basis, i.e. the conditions set out in the OECD Council Act concerning Exchange of Confidential Data on Chemicals [C(83)97(Final)] apply to the experts in each country that receives the data.

It is recommended that this form be completed in English.

When filling in the form, please also read "Guidance for collection and transmission of exposure information for SIDS Initial Assessment" (Section 2.5 of the SIDS Manual) and follow the instructions described in the guidance as well as those written in this format.

CAS No: _____ **Country:** _____

EXPOSURE INFORMATION FOR SIDS INITIAL ASSESSMENT

1. IDENTITY OF CHEMICAL

1.1 CAS No.:

1.2 Chemical name:

2. GENERAL INFORMATION CONCERNING PRODUCTION AND USE

2.1 Quantity (tonnes/year) *(Most recent year's record. Plural years' records could also be described.)*

Year	Production (a)	Import (b)	Export (c)	Total (a+b-c)

2.2 Use pattern and approximate percentage of total volume in each use category *(Please use glossary codes for HEDSET, shown in the Annex to the guidance, as much as possible. Please also distinguish between the on-site use and the estimated off-site use with * for the latter.)*

Main Category	Industrial Category	Use Category	Approximate % of total

2.3 Details of process or processes involved *(e.g. continuous/batch, open/closed, whether water is involved in the process or cleaning the system.)*

CAS No: _____ **Country:** _____

3. OCCUPATIONAL EXPOSURE *(If different answers are expected for different processes, please show them separately. Please also distinguish exposure during production from that during occupational/professional use.)*

3.1 MAK or equivalent occupational standard *(mg/m^3 with time period)*

3.2 Protective measures employed *(Please clarify the industry category, process and/or activity.)*

3.2.1 Engineering control

3.2.2 Personal protection *(e.g. protective equipment)*

3.3 Other information

3.3.1 Product information

Industrial Category	Use of the product / preparation	Form of the product / preparation (e.g. aerosol, powder, liquid)	Wt % of the chemical in the product / preparation	Function of the chemical in product / preparation

3.3.2 Exposure scenarios *(Clarify the industrial category. Please also distinguish exposure during production from that during occupational/professional use.)*

3.3.2.1 Activities of relevance to exposure, and route and extent of exposure

3.3.2.2 Frequency and duration of Use *(days/year and hrs/day)*

3.3.2.3 Number of workers per site

3.3.2.4 Characteristics of exposed population *(e.g. gender, age)*

3.3.3 Summary of workplace monitoring data *[Please describe summary of related activity and sampling and analytical methods; year, number, range, median and 95%-percentile of data (mg/m^3), if possible.]*

4. ENVIRONMENTAL EXPOSURE

4.1 Release estimates from point sources *(Industrial sectors in which the chemical is manufactured, processed or used should be identified as industrial categories.)*

Industrial Category	**Approxi-mate number of sites**	**Industrial processes which are likely to generate releases to the environment** *(Distinguish manufacturing from processing or use)*	**Release estimates to each compartment (wt/year or qualitative distribution)**		
			Surface water	**Air**	**Soil**
Total					

4.2 Summary of monitoring data of emission *[Please clarify the source in conjunction with the above table. Please describe media, summary of sampling and analytical methods; year, number, range, median and 95%-percentile of data (mg/l, mg/g-dry or wet, mg/m^3), if possible.]*

CAS No: _____ **Country:** _____

4.3 Release estimates from off-site *(Please try to cover all the life cycle of chemicals.)*

Release from:	Approxi-mate % of total release	Industrial category or Use category or Form of waste	Processes likely to generate releases to the environment	Release estimates to each compartment (wt/year or qualitative distribution)		
				Surface water	Air	Soil
Small scale industry						
Consumer use						
Waste disposal						

4.4 Summary of environmental monitoring data *[Please see the instruction in 4.2. Please also clarify whether the data can be considered as background level or close to the contaminated site.]*

5. CONSUMER EXPOSURE *(Please fill in this table in conjunction with 2.2. Protected measures could also be described below the table. If no consumer use is expected, please skip this.)*

Use Categories for consumer use	Form of product *(e.g. aerosol, powder, liquid)*	Wt % of chemical in product and dilution factor for use	Function of the chemical in product	Condition of use, route and extent of exposure *(e.g. oral, dermal, inhalation; outdoors, indoors)*	Frequency and duration of use *(days/year and hrs/day)*

(Any protective measures)

CAS No: _____ **Country:** _____

6. REGULATORY INFORMATION *(to be filled in by SIDS Contact Points only)*

6.1 National regulatory standards *(purpose and value)*

6.2 Classification and Labelling *(Please describe them.)*

6.3 Other measures for management of exposure

7. OTHER INFORMATION WHICH WILL HELP TO FOCUS EXPOSURE ASSESSMENT *(Any other quantitative or qualitative information could be described here.)*

8. DATA SOURCES SEARCHED (REFERENCES) *(Please enter full details **including negative results**.)*

8.1 Data sources from industry

8.2 National data sources

8.3 International data sources

Annex 5

An Example of Procedure for Gathering and Documenting Use-related Information

The following list should be regarded as a draft "checklist" describing individual steps in the process of gathering and documenting use-related data. The "checklist" may vary according to the organisations (e.g. government, industry) or people involved in conducting the search.

1. Searching substance identity data

   - searching the CAS-Registry file (STN) (scientific substance identity)
   - searching internal documentations (e.g. product codes)

2. Gathering use-related information by searching suitable sources

   - searching governmental database (e.g. EXICHEM, product register, release inventory)
   - searching internal documentations (e.g. product catalogues, customer-related documentation)
   - selection of suitable customer firms in order to obtain a representative cross-section of use-related information using an agreed proforma. The use of an agreed proforma is intended to promote comparability of the information which is obtained and may serve to avoid demotivation in the consulted firms due to be confronted with different query models.
   - searching printed literature
     - searching standard reference books
     - searching bibliographic references of available original publications (reviews)
     - searching suitable electronic databases (e.g. on-line databases, CD-ROM publications)

3. Description of the work done

   - short description of the search strategy (e.g. description of the approach used in accessing the various sources)
   - description of the further development of the query formulation through the evaluation of the documents identified during the search

4. Documentation of search results

   - short description of the steps performed in the search procedure
   - negative results: list, including reference to the source
   - positive results: present, including reference to the source, and transfer to the data transfer format
   - ensure anonymity of source information where necessary (e.g. identity of customers)
   - brief assessment of search results (e.g. out-dated literature data)

Annex 6

Expressions for Quantity and Categories of Use Pattern

1. Quantity

Following range of quantity produced or imported are recommended to be used.

10	-	50	tonnes per annum
50	-	100	tonnes per annum
100	-	500	tonnes per annum
500	-	1 000	tonnes per annum
1 000	-	5 000	tonnes per annum
5 000	-	10 000	tonnes per annum
10 000	-	50 000	tonnes per annum
50 000	-	100 000	tonnes per annum
100 000	-	500 000	tonnes per annum
500 000	-	1 000 000	tonnes per annum
more than 1 000 000			tonnes per annum

Note: indicate the year when these quantities were produced or imported. If the annual figure is not for a calendar year, specify it in comment field.

2. Use Pattern

Data on use pattern are recommended to be given by assigning the following glossaries which is also used in HEDSET. There are 4 main groups according to their exposure relevance, 15 industrial categories and 55 use categories.

Type of Use - use **EACH** of following terms

- Main
- Industrial
- Use

A. Main Categories - use one of the following glossary codes

- Use in closed systems
- Use resulting in inclusion into or onto matrix
- Non dispersive use
- Wide dispersive use

Use in closed systems

A substance should be assigned only to this category if it remains within a reactor or is transferred from vessel to vessel through closed pipework and therefore accidental spillage is the only likely cause for human exposure or environmental contamination.

These intermediates are classified in one of the following 3 categories:

- non-isolated intermediates (restricted to the reaction vessel and its dedicated equipment)
- isolated intermediates stored on-site under controlled conditions
- isolated intermediates with controlled transport

A typical example is phosgene which will be used only under these conditions.

Substances that are used in closed systems but might be released into the environment after use, sometimes in considerable quantities, or where significant discharges into the environment cannot be excluded during production and use, should be assigned to the "Non dispersive use" or even "Wide dispersive use" categories.

Typical examples in the latter case are CFC's used as cooling agents or hydraulic fluids.

Use resulting in inclusion into or onto matrix

Use consisting of inclusion into or onto matrices means all processes where chemicals are incorporated into products or articles from which they would not be released into the environment. Examples are the inclusion of plasticizers in plastics, additives such as pigments or dyes in plastics or fibres and catalysts in coating materials.

Non dispersive use

Non dispersive use refers to chemicals which are used in such a way that only certain groups of workers, with the knowledge of the processes, come into contact with these chemicals. Workers are normally aware of the procedures to protect themselves through the use of personal or technical protective measures. The employer should also take the necessary steps to protect the environment against exposure. Thus, exposure to these chemicals will be limited.

These chemicals may also be discharged into the environment from point sources. Quantities discharged will be limited due to protective measures such as waste water sewage treatment plants or air filters.

Wide dispersive use

The term "wide dispersive use" should be used for a wide range of activities particularly where end users come into contact with the products.

Examples are detergents, cosmetics, disinfectants, solvents in household paints

B. Industrial Categories - use the following glossary codes

- Agricultural industry: e.g. Pesticides, fertilisers
- Basic chemical industry: basic chemicals e.g. Solvents, pH-regulating agents (acids, alkalis)
- Chemical industry: chemicals used in synthesis e.g. Intermediates (including monomers), process regulators
- Electrical/electronic engineering industry: e.g. Electrolytes, semiconductors. Not: galvanics, electroplating agents
- Fuel industry: e.g. Gasoline, colouring agents, fuel additives, antiknock agents
- Leather processing industry: e.g. Dyestuffs, tanning auxiliaries
- Metal extraction, refining and processing industry: e.g. Heat transferring agents, electroplating agents
- Paints, lacquers and varnishes industry: e.g. Solvents, viscosity adjusters, dyestuffs
- Paper, pulp and board industry: e.g. Dyestuffs, toners
- Personal and domestic use: e.g. Consumer products such as detergents (including additives), cosmetics, non-agricultural pesticides for domestic use
- Photographic industry: e.g. Antifogging agents, sensitises
- Polymers industry: e.g. Stabilisers, softeners, antistatic agents, dyestuffs
- Public domain: e.g. Professional products used in public areas such as non-agricultural pesticides, cleaning agents
- Textile processing industry: e.g. Dyestuffs, flame retardants

- Other (indicate the category)

These 15 categories represent almost all industrial uses for chemicals and could serve for setting up exposure scenarios with regard to the designated use of a substance.

C. Use Categories - use the following glossary codes

- Absorbents and Adsorbents
- Adhesive, binding agents
- Aerosol propellants
- Anti-condensation agents
- Anti-freezing agents
- Anti-set-off and anti-adhesive agents
- Anti-static agents
- Bleaching agents
- Cleaning/washing agents and disinfectants
- Colouring agents
- Complexing agents
- Conductive agents
- Construction materials additives
- Corrosion inhibitors
- Cosmetics
- Dustbinding agents
- Electroplating agents
- Explosives
- Fertilisers
- Fillers
- Fixing agents
- Flame retardants and fire preventing agents
- Flotation agents
- Flux agents for casting
- Foaming agents
- Food/foodstuff additives
- Fuel
- Fuel additives
- Heat transferring agents
- Hydraulic fluids and additives
- Impregnation agents
- Insulating materials
- Intermediates (give description in the remarks field)
- Laboratory chemicals
- Lubricants and additives
- Non-agricultural pesticides,
- Odour agents
- Oxidising agents
- pH-regulating agents
- Pesticides
- Pharmaceuticals
- Photochemicals
- Process regulators
- Reducing agents
- Reprographic agents
- Semiconductors
- Softeners
- Solvents
- Stabilisers
- Surface-active agents
- Tanning agents
- Viscosity adjusters
- Vulcanising agents
- Welding and soldering agents
- Others (indicate the category)